

Package leaflet: Information for the user

Uniroid-HC® suppositories

hydrocortisone 5 mg + cinchocaine hydrochloride 5 mg



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Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Uniroid-HC suppositories are and what they are used for
2. What you need to know before you use Uniroid-HC suppositories
3. How to use Uniroid-HC suppositories
4. Possible side effects
5. How to store Uniroid-HC suppositories
6. Contents of the pack and other information

1. What Uniroid-HC suppositories are and what they are used for

Uniroid-HC suppositories contain hydrocortisone and cinchocaine hydrochloride.

- Hydrocortisone soothes and relieves irritations and inflammation of the skin.
- Cinchocaine hydrochloride, a local anaesthetic, provides pain relief.

They are used to treat:

- internal haemorrhoids (piles), providing short-term relief of pain, irritation and associated itching around the back passage (anus).

2. What you need to know before you use Uniroid-HC suppositories

Do not use Uniroid-HC suppositories:

- If you are allergic to hydrocortisone, or to any other steroids
- If you are allergic to cinchocaine, or to any other local anaesthetics
- If you are allergic to any other ingredients of this medicine (listed in section 6)
- If you have tuberculosis
- If you have any kind of skin infection (e.g. thrush of the back passage, viruses affecting the skin).

Warnings and precautions

Talk to your doctor before using Uniroid-HC suppositories:

- If you have had a bad reaction to this or similar products before
- If you are pregnant or planning a pregnancy
- If you are breast-feeding.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

Do not use the suppositories in children under 12 years of age unless directed by the doctor.

Other medicines and Uniroid-HC suppositories

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by Uniroid-HC or they may affect how well Uniroid-HC will work.

Some medicines may increase the effects of Uniroid-HC suppositories and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV containing cobicistat).

Pregnancy and breast-feeding

Do not use the suppositories if you are pregnant or breast-feeding unless advised by your doctor. If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

3. How to use Uniroid-HC suppositories

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults, elderly and children over 12 years: insert one suppository

Continued over page

twice a day (morning and evening) and after each time you empty your bowels, unless your doctor has told you otherwise.

Do not use the suppositories for more than 7 days. If the problem is no better, tell your doctor.

Children under 12 years: this medicine is NOT suitable for children under 12 years.

Administration:

1. Wash your hands before and after use. Avoid excessive handling of the suppository, as it is designed to melt at body temperature.
2. Tear one wrapped suppository from the strip and, while holding it with the tip facing upwards, peel away the foil from both sides.
3. Insert the suppository as far as possible into the back passage (anus).

If you use more Uniroid-HC suppositories than you should

If you insert too many suppositories or accidentally swallow them:

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the carton and any remaining suppositories with you so that people can see what you have used or taken.
3. Do this even if you feel well.

If you forget to use

If you forget to use a suppository, use it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not use a double dose to make up for a missed dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Uniroid-HC suppositories can cause side effects, although not everybody gets them.

Tell your doctor if you get the following side effect:

- blurred vision or other visual disturbances
- an allergic reaction such as itching, pain or rash around the back passage
- irritation around the back passage.

Large doses and regular use may suppress the adrenal glands.

2/L/I/10

This may cause complex changes in your body. If you use Uniroid-HC suppositories regularly, discuss this with your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Uniroid-HC suppositories

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the foil and on the carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Uniroid-HC suppositories contain

- The active ingredients are hydrocortisone 5 mg and cinchocaine hydrochloride 5 mg.
- The other ingredient is hard fat.

What Uniroid-HC suppositories look like and contents of the pack

Uniroid-HC suppositories are off-white smooth suppositories. They are available in packs of 10 and 12 suppositories. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd.,
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